U.S. Department of Justice

United States Attorney
Southern District of New York

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March 21, 2014

BY ECF

Honorable Colleen McMahon
United States District Judge
U.S. Courthouse, 500 Pearl Street
New York, NY 10007

Re: *United States* ex rel. *Kester v. Novartis Pharmaceuticals, Corp.*, 11 Civ. 8196 (CM) (JCF)

Dear Judge McMahon:

In accordance with Your Honor's March 14th Order, we write respectfully to explain why the fraud allegations in the United States's (the "Government") Amended Complaint-in-Intervention ("Am. Compl.") fully satisfy the requirements of Rule 9(b).

The Anti-Kickback Statute ("AKS") forbids offering or giving any type of "remuneration" to "induce" a person to "recommend" a drug or service covered by a federal healthcare program. *See* 42 U.S.C. § 1320a-7b(b)(2). Further, since 1994, the Government has given ample notice to drug-makers like Novartis that offering "cash or other benefits" to induce "*pharmacies* … to help persuade physicians … to change prescriptions" or perform marketing tasks such as "sales-oriented 'education' or 'counseling' contacts" can violate the AKS. 59 Fed. Reg. 65,372, 65,376 (Dec. 19, 1994) (emphasis added).

Novartis, however, recognized that certain pharmacies had influence with doctors and/or over patients. So it used rebates and patient referrals, which are remuneration under the AKS, to induce those ostensibly independent pharmacies to recommend its drugs. Here, the Government alleges two such kickback schemes – one for the transplant drug Myfortic, and the other for the iron chelation drug Exjade.[1] In the Myfortic scheme, Novartis offered rebates to pharmacies on the condition that they recommend that doctors switch transplant patients to Myfortic or not use generic drugs that compete with Myfortic. In the Exjade scheme, Novartis controlled patient referrals through a closed distribution network it had created, and it used its control over whether BioScrip had access to Exjade patients to induce the pharmacy to recommend refills to Exjade patients. Both schemes, as the Amended Complaint explains, followed a basic pattern:

- Novartis offered rebates or patient referrals to pharmacies that, as Novartis recognized, had influence over doctors and/or patients;
- Novartis conditioned those incentives on the pharmacies agreeing to use their influence to recommend the use of Novartis's drugs to doctors and/or patients;
- The pharmacies made the recommendations per their arrangements with Novartis, and Novartis monitored how effectively the pharmacies were in terms of getting doctors to switch patients to Myfortic or getting patients to order refills; and
- Novartis gave the pharmacies rebates and/or additional patient referrals as rewards

[1] Novartis already answered the Myfortic allegations in the Government's original complaint. [Dkt. 18]. So it has no basis to complain now about lacking notice of those allegations.

and further inducements to switch prescriptions to Myfortic, to keep patients on Myfortic, or get Exjade refill orders.

Consistent with Rule 9(b), the Amended Complaint details how Novartis's two kickback schemes caused pharmacies to submit claims to Medicare and Medicaid. *See, e.g.*, Am. Compl. ¶ 82 (as part of the Myfortic scheme, Bryant's Pharmacy submitted 8,300 plus Myfortic claims to Medicare). Those claims were false under the False Claims Act, 31 U.S.C. § 3731 *et seq.* ("FCA"), because they were "tainted by a kickback arrangement." *U.S. ex rel. Freedman v. Suarez-Hoyos*, 2012 WL 4344199 at *4 (M.D. Fla. Sept. 21, 2012). This is because compliance with the AKS is "clearly a condition of payment" by Medicare and Medicaid, *U.S. ex rel. Wilkins v. United Healthcare*, 659 F.3d 295, 313 (3d Cir. 2011); *New York v. Amgen Inc.*, 652 F.3d 103, 111-13 (1st Cir. 2011); and "when the conditions are not satisfied, nothing is due." *United States v. Rogan*, 517 F.3d 449, 453 (7th Cir. 2008).

Novartis asserts the Government must allege that, without recommendations from the pharmacies, transplant doctors would not have prescribed Myfortic, and Exjade patients would not have ordered refills. This is wrong. Neither Rule 9(b) nor the AKS imposes such a requirement at the pleading stage, and Novartis cites no case to support its assertion. Indeed, under the FCA, the Government can recover on claims submitted as part of a kickback scheme without having to prove a lack of medical necessity. *Rogan*, 517 F.3d at 453.

Finally, Novartis also is liable under the FCA because it knew that its kickback schemes "cause[d]" pharmacies to use false certifications and representations to obtain Medicare and Medicaid reimbursements. 31 U.S.C. § 3729(a)(1)(B) (imposing liability on "any person who … knowingly … causes to be made or used [] a false [] statement material to a false or fraudulent claim"). Here, Novartis gave kickbacks to pharmacies in exchange for recommending Myfortic and Exjade; and it was aware that those pharmacies, in turn, used false certifications and representations claiming compliance with laws like the AKS to get federal reimbursements. Novartis, thus, is liable for the claims submitted by those pharmacies. *Rogan*, 517 F.3d at 451.

The Myfortic Scheme

The Amended Complaint alleges Novartis offered twenty or more pharmacies kickbacks in exchange for recommending Myfortic to doctors, and details how five of the arrangements operated. The allegations as to Bryant's Pharmacy illustrate all four key elements of the scheme:

- *Selecting Pharmacies That Have Influence with Doctors*: In 2005, Novartis offered a kickback relationship to Bryant's in recognition of its influence with transplant doctors. Novartis knew that Bryant's owner had strong ties to "the State Kidney Commission" and also was a member of "the formulary committee for the largest MCO [managed care organization] in the State." Am Compl. ¶ 72.[2]

- *Tying Rebates to Switching Patients*: Novartis offered Bryant's the opportunity to earn significant rebates and discounts – up to 15% of its total Myfortic sales. In exchange, as Novartis records show, the pharmacy owner was to "move patients from

[2] As alleged in the Amended Complaint, each key aspect of Novartis's relationship with Bryant's also was present in the other Myfortic kickback relationships. *See, e.g.*, Am. Compl. ¶¶ 87, 95, 103, 117 (Novartis was aware that the Baylor, Kilgore's, Transcript, and Twenty-Ten pharmacies could influence doctors to switch patients to Myfortic).

CellCept [Myfortic's then-main competitor] to Myfortic." *Id.*[3]

- *Tracking the Results*: Once this kickback relationship began, Novartis closely monitored Bryant's Myfortic and CellCept sales to track how many patients it caused to switch from CellCept to Myfortic. For example, Novartis saw that, "in 3 months," Bryant's was able "to convert [*i.e.*, switch] all patients from CellCept to Myfortic." Novartis also knew that the pharmacy used its influence with "[area] doctors" to "control [Myfortic] market share" and "to increase Myfortic utilization." *Id.* ¶ 74.

- *Paying Pharmacies Rebates for Recommending Myfortic*: The kickback relationship was highly lucrative for Novartis. "In the [first] four years," Novartis saw a tenfold increase in Bryant's annual Myfortic sales, rising "from $100,000 to over $1 million." Novartis, in turn, gave Bryant's over $650,000 in rebates between 2005 and March 2013 as reward and as further inducements to promote Myfortic. *Id.* ¶ 75, 70.[4]

The Exjade Scheme

In early 2007, Novartis realized that Exjade's frequent side effects and changing patient population were causing refill orders to decline. *Id.*¶ 168-70. That had led to a big "performance gap" between actual Exjade sales and Novartis's sales target. *Id.* ¶ 170-173. In response, Novartis implemented its kickback arrangement with BioScrip:

- *Assessing BioScrip's Influence Over Patients*: in February 2007, Novartis placed BioScrip under a PIP ("performance improvement plan") — requiring BioScrip to show that it could increase the refill level among its Exjade patients and convince patients who had stopped getting refills to resume ordering. Novartis also made BioScrip provide weekly updates on its refill orders and "restarts." *Id.* ¶¶ 173-76.

- *Conditioning BioScrip's Access to Patient Referrals on Generating Refills*: BioScrip had to submit to those demands because Novartis controlled who had access to Exjade patient referrals, which were highly valuable to BioScrip. Indeed, Novartis told BioScrip that, if it failed to increase its refill levels, it risked being removed from EPASS and thus losing access to Exjade patients. *Id.* ¶ 177; *see also* BioScrip Settlement Stipulation, ¶ 2.g [Dkt. 41] (BioScrip admitting that Novartis made this threat in February 2007 as part of the PIP).

- *Tracking BioScrip's Results*: To satisfy Novartis, BioScrip had its pharmacy staff call patients to offer purported "clinical education" and "counseling" about Exjade therapy. The advice, however, was designed to get patients to order refills and,

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[3] *See also, e.g.*, Am. Compl. ¶ 86 (Novartis extracting commitment by Baylor to convert "25% of the patients [to Myfortic] by March and 100% conversion by May").

[4] After 2009, when generic CellCept became available, Novartis used kickbacks to induce Bryant's to keep patients on Myfortic by "argu[ing]" against the use of generic CellCept. *See* Am. Comp. ¶¶ 76-80. For example, in October 2009, Bryant's owner told Novartis that unless the terms of their arrangement were modified, he would stop advising a doctor against the use of generic CellCept on purported clinical grounds, but instead recommend all of his "current Myfortic patients convert to generic [CellCept]." *Id.* ¶ 78. Novartis knew that the probability for Bryant's to convince the doctor "to convert all Myfortic patients to generic is 100%," so Novartis agreed to the modification to keep Bryant's its "staunch ally." *Id.* ¶¶ 79-80.

further, was one-sided in that it emphasized Exjade's benefits without discussing the drug's more serious side effects. *See* Am. Comp. ¶¶ 178-81. The Exjade marketing team at Novartis was directly involved in deciding how BioScrip would advise patients, and it also closely tracked BioScrip's results through weekly updates and/or monthly reports. *Id*. ¶ 183.

- *Giving BioScrip Patient Referrals and Rebates as Further Inducements*: By late 2007, Novartis recognized that BioScrip had become very effective in generating refills. For Novartis, "an Exjade patient [at] BioScrip is worth $800-$2,800 more than a patient serviced by another pharmacy." *Id*. ¶ 185. To ensure that it would carry on promoting Exjade refills to patients, Novartis gave BioScrip a bundle of benefits, including more patient referrals and higher rebates. *Id*. ¶¶ 186-92. BioScrip, in turn, committed to "mirror and support Novartis['s] priorities," and it continued to recommend Exjade refills to patients without discussing the drug's increasingly clear risks of serious side effects. *Id*. ¶¶ 193, 210-12.

Novartis carried out this kickback arrangement until May 2012 (when BioScrip sold its specialty pharmacy), and the scheme caused BioScrip to direct its efforts to promoting Exjade refills for Novartis. *Id*. ¶¶ 197-98. As a former BioScrip supervisor explained, Novartis's "system of tying rebates and patient referrals to the number of refill shipments caused [BioScrip] to be focused exclusively on the number of orders and refill rates, rather than on patient care." *Id*. ¶ 208.

The Government's FCA Claims Against Novartis Have the Requisite Specificity

Novartis claims to lack sufficient notice under Rule 9(b) about what false claims its two schemes caused pharmacies taking kickbacks to submit to Medicare and Medicaid. However, Rule 9(b) does not require the Government to "identify particular claims resulting from the kickback scheme," *U.S. ex rel. Parikh v. Citizens Med. Ctr.*, 2013 WL 5304057, at *7 (S.D. Tex. Sept. 20, 2013); instead, it only requires "particular details of a scheme … paired with reliable indicia that lead to a strong inference that claims were actually submitted." *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009); *accord United States v. Huron Consulting Group, Inc*., 2011 WL 253259, at *2 (S.D.N.Y. Jan. 24, 2011).

The Government more than satisfies that requirement, as the Amended Complaint identifies many examples of false claims. It alleges that Novartis knew that Medicare and Medicaid were key sources of reimbursements for both Myfortic and Exjade. *See* Am Comp. ¶¶ 39-49. It also details (*i*) which pharmacies taking kickbacks from Novartis submitted claims, (*ii*) how many kickback-tainted claims were submitted, (*iii*) for which drug, (*iv*) to which federal healthcare program(s), and (*v*) over what time periods. *See*, *e.g.*, *id*. ¶ 82 (Bryant's submitted approximately 8,300 Myfortic claims to Medicare between 2005 and March 2013), ¶ 229 (BioScrip submitted approximately 37,900 Exjade claims to Medicare and approximately 4,800 claims to New York Medicaid between February 2007 and May 2012). Finally, the Amended Complaint offers ample basis to infer that those claims were tainted by kickbacks and thus false.

Take Bryant's as an example. Novartis knew that "73% of [Bryant's] patients are [on] Medicare." *Id*. ¶ 46. Novartis also knew that, in exchange for rebates, Bryant's drove up its Myfortic sales tenfold by "converting all [its] patients … to Myfortic" in 2005 and by using its influence with doctors to "control [Myfortic] market share." *Id*. ¶ 74. Further, after 2009, Novartis induced Bryant's to keep patients on Myfortic by "argu[ing] against" the use of generic

CellCept. *Id*. ¶¶ 77-80. Thus, all or nearly all of the 8,300-plus Myfortic claims Bryant's submitted to Medicare during the kickback relationship were "tainted by [the] kickback arrangement" and false as a matter of law.[5] *See Suarez-Hoyos*, 2012 WL 4344199, at *4.

Likewise, the false claims that Novartis caused BioScrip to submit as part of the Exjade scheme are pled with requisite specificity under Rule 9(b). As noted above, Novartis conditioned BioScrip's access to Exjade patients on the pharmacy's commitment to promoting refills as part of Novartis's Exjade sales and marketing efforts. *See* Am. Compl. ¶¶ 177-85. These patient referrals were a key part of the kickbacks Novartis used to induce BioScrip to recommend Exjade refills. *Id*. ¶¶ 144-45. Where, as here, a kickback scheme involves patient referrals, it renders all the Medicare and Medicaid claims for the patients referred through the scheme false.[6] *See Rogan*, 517 F.3d at 453; *United States v. Health Alliance of Greater Cincinnati*, 2008 WL 5282139, at *12 (S.D. Ohio Dec. 18, 2008).

Finally, Novartis's contention that it lacks notice of the Government's theory as to the additional pharmacies in the Myfortic scheme (besides Bryant's and the other four examples) strains credulity. The Amended Complaint explains – based on Novartis's own records and testimony of its own employees – that, since 2005, it has been a basic strategy for Novartis to use rebates to induce pharmacies to recommend switching patients to Myfortic. *See* Am. Compl. ¶¶ 122-28. Indeed, Novartis continued to pursue this strategy even after knowing that it "cannot put [] in writing" its discussions about using the Walgreens pharmacy to switch patients to Myfortic. *Id*. ¶¶ 134-36. These allegations, together with the detailed facts about Novartis's arrangements with the five example pharmacies, fully satisfy Rule 9(b). *See United States v. Wells Fargo Bank, N.A.*, 2013 WL 5312564, at *16 (S.D.N.Y. Sept. 24, 2013) (10 examples of recklessly underwritten loans sufficient to support allegations of a scheme involving thousands of loans).

Novartis Misconstrues the Meaning of "Resulting From" in 42 U.S.C. § 1320-7b(g)

Novartis contends that 42 U.S.C. § 1320a-7b(g),[7] a section of the AKS that Congress enacted in 2010 as part of the Affordable Care Act, requires the Government to allege and show that the kickback scheme caused a physician or patient to make a prescription or ordering decision that he or she would not have made otherwise. Novartis is wrong.

Congress promulgated 42 U.S.C. § 1320a-7b(g) to remove any doubt that AKS violations give rise to FCA liability. That provision's legislative history "evinces Congress' intent to clarify, not alter, existing law that claims for payment made pursuant to illegal kickbacks are false under the [FCA]." *U.S. ex rel. Westmoreland v. Amgen, Inc*., 812 F. Supp. 2d 39, 52-53 (D. Mass. 2011). Thus, neither § 1320a-7b(g) nor Rule 9(b) requires the Government to allege a

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[5] The Government has produced to Novartis Medicare Part B claims data for Myfortic, CellCept, and generic CellCept, including data for the 8,300-plus claims submitted by Bryant's.

[6] Novartis may mischaracterize the claims from Bryant's and BioScrip as mere "aggregate expenditure data." But the difference between this case and cases like *U.S. ex rel. Ge v. Takeda Pharm. Co*., 737 F.3d 116 (1st Cir. 2013) could not be more stark. Here, the Government clearly explains the connection between the claims and the kickback schemes. By contrast, the relator in *Ge* "alleged next to no facts" to connect the "alleged misconduct" with false claims. *Id*. at 124.

[7] This section provides that "[i]n addition to the penalties provided for in this section or section 1320a-7a of this title, a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the FCA]."

specific causal link at the pleadings stage. *See Wilkins*, 659 F.3d 295, 313 (3d Cir. 2011) (to overcome a motion to dismiss, a FCA complaint "need not allege a relationship between the alleged AKS violations and the claims [] submitted to the Government").

More basically, Novartis cannot evade liability by positing that doctors or patients would have made the same decision in the absence of any influence by pharmacies taking kickbacks from Novartis. Congress recognized the difficulty inherent in proving, after the fact, that a kickback had affected a medical decision, and enacted the AKS precisely to relieve the Government of the burden of proving the lack of medical necessity on a case-by-case basis. *See* H. Rep. 95-393, at 47. Thus, as Judge Easterbrook explained in *Rogan*, the Government is entitled to recover under the FCA for claims made as part of a kickback scheme irrespective of whether the Government "would have paid for [the] care" if "patients had gone elsewhere," *e.g.*, to a pharmacy not taking kickbacks. 517 F.3d at 453. Adopting Novartis's tortured construction of § 1320a-7b(g), by contrast, would effectively put the Government "in the position of funding illegal kickbacks," *see Westmoreland*, 812 F. Supp. 2d at 50, and frustrate the False Claim Act's remedial purpose. *See U.S. ex rel. Feldman v. Van Gorp*, 697 F.3d 78, 87 (2d Cir. 2012) (the FCA is intended to "make the government completely whole for money taken from it by fraud").

The Amended Complaint Specifically Alleges the Use of False Certifications and Representations as Part of the Two Kickback Schemes

As discussed above, the claims submitted by pharmacies taking kickbacks are "factually false" under *Mikes v. Strauss*, 274 F.3d 687, 696-99 (2d Cir. 2001) because "the Government does not get what it bargained for when a defendant is paid [] for services tainted by a kickback." *See Wilkins*, 659 F.3d at 314. In addition, the Government also alleges those claims are "legally false" because the kickback schemes caused the pharmacies to use false certifications and representations. This provides another basis for holding Novartis liable under the FCA. A claim is "legally false" if it involves use of a certification or representation of compliance with a statute or regulation, and the certification or representation is false. *See Mikes*, 274 F.3d at 696-99.

Here, the Amended Complaint alleges that the pharmacies taking kickbacks from Novartis all made false certifications or representations regarding their compliance with the AKS. To be eligible for Medicare Part B payments for Myfortic, pharmacies like Bryant's had to certify that they will "abide by … all applicable Medicare laws, regulations, and program instructions" and that they "understand payment … by Medicare is conditioned on … complying with such laws, regulations, and program instructions (including … the [AKS])." Am Comp. ¶ 23. Moreover, to obtain reimbursements under Medicare Part D and Medicaid, pharmacies like BioScrip represented or certified that they would comply with applicable federal and state laws and regulations. *See id*. ¶¶ 28-29, 36-38.

Those certifications were at odds with the pharmacies' actual conduct – Novartis induced them to violate the AKS by recommending Myfortic and Exjade in exchange for rebates and/or patient referrals. *See id*. ¶¶ 60-70, 143-50. Thus, those pharmacies' certifications were false. *See U.S. ex rel. Schmidt v. Zimmer*, 386 F.3d 235, 243 (3d Cir. 2004); *Amgen*, 652 F.3d at 110-16. Because the Medicare and Medicaid claims submitted by the pharmacies were based on their certifications, all these claims are false for purposes of the FCA, and Novartis is liable under the FCA for these false claims. *See Rogan*, 517 F.3d at 451; *U.S. ex rel. Anti-Discrimination Ctr. v. Westchester County*, 2009 WL 1108517, at *3 (S.D.N.Y. Apr. 24, 2009); *see also United States v. First Nat'l Bank of Cicero*, 957 F.2d 1362, 1374 (7th Cir. 1992).

We thank the Court for its consideration of this letter.

Respectfully,

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